REMARKS

Claims 14, 17, 19, 20, 32-34, 36-38, 40-42, 45, 48 and 50-53 are pending in the application with entry of this Amendment. Claims 14, 17, 32-34, 40 and 51-53 are currently amended, and claims 46-47 are currently canceled without prejudice. The amendments and new claims do not present new matter. *See, e.g.*, claims as filed; Figs. 33-36. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that the following rejections of the May 28, 2009 Office action were withdrawn following the Amendment submitted on August 28, 2009:

A. Rejection of claims under 35 U.S.C. §112¶1.

B. Rejection of claims under 35 U.S.C. §103(a) over U.S. Patent No. 4,144,890 to Hess ("Hess") in view of U.S. Patent No. 6,228,082 to Baker *et al.* ("Baker").

C. Rejection of claims under 35 U.S.C. §103(a) over U.S. Patent No. 4,4,685,466 to Rau ("Rau") in view of U.S. Patent No. 5,466,255 to Franchi ("Franchi") and U.S. Patent No. 6,091,975 to Daddona ("Daddona").

D. Rejection of claims under 35 U.S.C. §103(a) over Rau, in view Franchi, Daddona and Baker.

II. Office Action Remarks Regarding Structural Limitations Being Functional Limitations and Identifying Means Believed to Correspond to Certain Limitations

Claims 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-50 stand rejected under 35 U.S.C. §112¶2 as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. There are multiple errors and inconsistencies with the rejection.

It is alleged in the Office Action, p. 2, that "stimulation element too small to form a transmural myocardial lesion" is a "functional" limitation." Such allegations and the rejection are improper and cannot support the rejection for various reasons.

First, such a limitation is clearly directed to a structural attribute, namely, the size of the stimulation element, such size being too small to form a transmural myocardial lesion. A claim limitation that is clearly structural since it is directed to a structural and physical characteristic of a component cannot simply be re-classified as a functional limitation as a matter of convenience.

Second, the Examiner has cited no case law or other authority stating that a structural attribute of a component of an apparatus is properly construed as a functional limitation.

Third, the Office Action remarks fail to address the fact that the independent claims 32 and 33 recite other structural aspects of a tissue stimulation element that are related to the same structural limitations discussed above. Specifically, claims 32 and 33, for example, recite *inter alia* "a tissue stimulation element having a diameter of about 0.5mm to 1.0mm ...". Claims 41 and 46 also recite dimensions of a tissue stimulation element. Thus, by the Office Action logic noted above, it is apparently alleged that a tissue stimulation element having a diameter of about 0.5mm to about 1.00mm, such diameters being too small to form a transmural myocardial lesion as explained by the specification, is also functional since this is the dimension of the same stimulation element discussed above.

Fourth, no case law or other authority is cited to support allegations that specific structural dimensions of an apparatus, which are clearly structural limitations, are instead functional limitations.

Fifth, not only do the claims recite structural attributes of a stimulation element, and even specific dimensions as noted in point 3 above, but claims 32-34 also recite that a tissue stimulation element is configured to emit non-ablative stimulation energy such that when non-ablative energy is emitted from a stimulation element that is too small to form a lesion (and having dimensions recited in claims 32 and 33), the combination of such non-ablative energy and such a small-sized stimulation element would not result in formation of a lesion, as the Examiner has aptly noted. Thus, the remarks in the Office Action actually support the conclusion that the claims do in fact particularly point out and distinctly claim the subject matter regarded as the invention when other claim limitations related to those same structures are properly considered. Thus, while the Office Action has cited only specific words of the claims, the Office Action remarks do not address other claim limitations that are directly related to that same structure, that address the Office Action's remarks, and that clearly render the rejection moot.

Sixth, even assuming the Office Action argument despite the clear structural attributes discussed above, the Office Action has cited no case law or authority stating that a functional limitation renders a claim indefinite under 35 U.S.C. §112¶2.

Seventh, the Office Action, p. 2, includes remarks stating that the Examiner believes that §112¶6 applies and what the Examiner believes to be structure corresponding to "means,

associated with the tissue stimulation element, for securing ..." By such remarks, the Examiner is apparently conceding that such a claim is not indefinite. Further, it is not clear how such remarks relate to or support the rejection under 35 U.S.C. §112¶2.

Eighth, even assuming the Office Action remarks of the seventh point discussed above, the Office Action has cited no case law or authority stating that if the Examiner believes that 112, sixth paragraph has been involved, the claim is indefinite for this reason, which is what is apparently implied in the Office Action, p. 2, since such remarks are included in the rejection under 35 U.S.C. §112¶2.

Ninth, in order to advance prosecution despite the shortcomings noted above (noting again that claims 33-34 already recite limitations directed to specific dimensions and non-ablative energy), claims 32-34 are amended to recite the tissue stimulation element being structurally configured to not form a transmural myocardial lesion when non-ablative energy is delivered to and emitted from the tissue stimulation element, which address the Examiner's remarks on page 2 that refer to size, configuration and energy, thus rendering the rejection moot for yet another reason.

Tenth, the rejection should be withdrawn in view of the remarks presented in the prior amendment, which noted various other sections of the MPEP that support Applicant's conclusion, particularly in view of claims 31-33 as amended. MPEP §2173.02 ("a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible"), citing *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence"). MPEP §2173.05(a) ("If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more.").

Accordingly, it is respectfully submitted that the rejection of claims 14, 17, 19, 20, 32-34, 37, 37, 40-42 and 45-50 under 35 U.S.C. §112¶2 is moot and be withdrawn.

III. Claims 14, 17, 32-34, 36-37, 40-42, 45, 48 and 50-51 Are Patentable Over Hess and Edwards

Independent claims 32-34 and respective dependent claims 14, 17, 36, 37, 40-42, 45, 48 and 50-51 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hess in view of a new reference, U.S. Patent No. 5,398,683 to Edwards *et al.* ("Edwards). Edwards is cited for the first time in the December 28, 2009 Office Action. Applicant respectfully submits that the rejection is moot.

It is conceded that Hess fails to disclose a tissue stimulation electrode of certain dimensions as recited in various claims. Office Action (p. 4). Thus, it is Applicant's understanding that it is also conceded that Hess fails to disclose dimension limitations and limitations directed to stimulation elements being too small to form a transmural myocardial lesion of claims 32, 33 and 41.

It is also conceded that Hess fails to disclose a second tissue stimulation element, consistent with the particular structure described and illustrated by Hess. Thus, it is Applicant's understanding that it is conceded that Hess fails to disclose "first and second stimulation elements" as recited in claims 14, 17, 32-34, 40, 41, 48 and 50.

Hess also fails to disclose, and is not related to, "means, associated with the first and second tissue stimulation elements, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure at a first tissue structure location and pressing the first and second stimulation elements against the single side of the tissue structure at respective second and third tissue structure locations different than the first tissue structure location, wherein neither of the first and second stimulation elements has a sharpened end and both of the first and second stimulation elements are positioned relative to the means for securing the surgical apparatus to the tissue structure such that the first and second tissue stimulation elements are pressed against the single side of the tissue structure and do not pierce the tissue structure" as recited in claim 32; "an anchor carrying the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue at a first location and to press the first and second stimulation elements against the tissue at respective second and third locations different than the first location, wherein neither of the first and second stimulation elements has a sharpened end and both of the first and second stimulation elements are positioned relative to a portion of the anchor that pierces tissue such that the first and second

tissue stimulation elements are pressed against the tissue and do not pierce the tissue" as recited in claim 33, and "a flexible carrier movable between an unstressed state and a deflected and stressed state and including a first end portion that carries the first tissue stimulation element, a second end portion that carries the second tissue stimulation element, and a curved interior portion located between the first and second end portions and configured such that the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state, wherein the carrier is configured to press the first tissue stimulation element and the second tissue stimulation element against the tissue surface when in the deflected and stressed state, wherein the first stimulation element and the second stimulation element do not have sharpened ends such that the first stimulation element and the second stimulation element are pressed against the tissue surface without piercing the tissue surface" as recited in claim 34.

With regard to these limitations, the Office Action refers to Hess, col. 3, lines 36-52 (which also refers to FIGS. 4-6) and FIG. 7. FIGS. 4 (as an example) and 7 are reproduced below for the Examiner's reference.

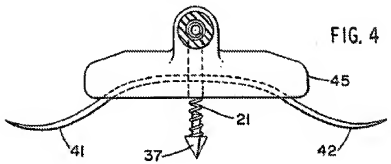

FIG. 4

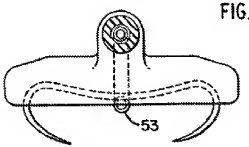

FIG. 7

With reference to Hess, FIGS. 4 and 7 above, the cited reference explains "an analogous construction to that illustrated in FIGS. 4-6 can be devised in which the attaching prongs extend

inwardly and the base is folded back rather than forward as in the illustrated embodiment. This is illustrated in FIG. 7. Hess (col. 3, lines 36-40) (emphasis added). Thus, while Hess discloses other configurations, all of the configurations involve tissue piercing members, which may be outwardly facing piercing members or barbs 41, 42 (as shown in FIG. 4) or inwardly facing piercing members or barbs (as shown in FIG. 7).

Edwards is cited as disclosing various conceded deficiencies of Hess. As noted in the Office Action, Edwards describes a medical catheter device having a pair of pacing electrodes 75 that are part of a catheter 10.

As shown in various figures, and as is well known in the art, the catheter 10 has a smooth rounded distal end for purposes of navigating vasculature within causing internal injury to the patient. For example, Edwards, FIG. 8, illustrates the pacing electrodes having an arcuate or curved shape such that they are flush and smooth with the outer cylindrical surface of the catheter shaft, which is consistent with the smooth, cylindrical configuration and known manner of positioning a catheter within a patient and into a heart.

On the basis that Edwards discloses two pacing electrodes, it is alleged in the Office Action, p. 4, last sentence, that it would have been obvious to modify Hess to use two small disk like electrodes. However, there are a number of issues with regard to Edwards and the simplistic argument that Applicant's claims are obvious just because Edwards discloses to pacing electrodes.

First, Hess, with reference to FIG. 7, describes a small, flat disk electrode that protrudes from a bottom surface of the central portion of the body with sharpened tips, whereas Edwards discloses pacing electrodes having an arcuate, non-flat or non-disc shape. In fact, Edwards illustrates these pacing electrodes as extending partially around a cylindrical catheter body. Thus, the Office Action's characterization of what Edwards discloses is not correct, and the Office Action is understandably silent as to why it would be obvious to utilize curved pacing electrodes of a catheter in a very different device that is used for a very different purpose, *i.e.*, to pierce tissue.

Second, claims 32-34 and various dependent claims recite first and second stimulation elements, but all of the structural configurations described by Hess involve two tissue piercing or stabbing elements, and the structure shown in Hess, FIG. 7 includes only one centrally disposed conductor 53. It is apparently the Examiner's argument that this conductor 53 would be replaced

by the cited small flat disk electrode that is mentioned in a single sentence by Hess. However, given the particular configurations described by Hess, there would be only one small flat disk electrode as opposed to two tissue stimulation elements as recited in the claims. The members of Hess, FIG. 7 that extend laterally are tissue piercing members, as discussed above. The Office Action allegation regarding combining Hess and Edwards ignores the particular structural configuration described by Hess.

Third, even if it were alleged that it would be obvious to include the tissue stimulation elements on the two tissue piercing members, the two tissue piercing members nevertheless pierce tissue. This is in contrast to Applicant's that claims recite the opposite structural configuration, *i.e.*, first and second stimulation elements are pressed against the single side of the tissue structure at respective second and third tissue structure locations and do not pierce the tissue structure.

Fourth, even though Hess discloses that in some cases a small flat disk electrode may be utilized, Hess does not provide any further details or illustration of this configuration. Thus, the Examiner relies on three lines of Hess without any further details to support the rejection or how such a configuration relates to the configurations recited in Applicant's claims. In this regard, Applicant notes that the rejection cannot stand based on what is not explicitly or inherently disclosed. MPEP §2112 (citations omitted) (fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic; to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities).

Fifth, all of the devices described by Hess are directed components that pierce tissue using sharp, needle-like members. As such, it would not be obvious to combine Edwards and Hess since Edwards and Hess describe devices that operate in different and opposite manners – Edwards describes a catheter with a smooth, rounded distal tip designed not to pierce tissue, whereas Hess describes tissue piercing members.

Further, while it is generally alleged, without more, that it would be obvious to add a second electrode to the system described by Hess despite Hess only referring to, and not even illustrating, a single disk electrode (and despite Edwards failing to disclose such an electrode), it

is not clear how, or why, this would be done, particularly considering that Hess does not suggest a need for a second disk electrode, particularly in view of the configuration shown in Hess, FIG. 7, in which the bottom face of the insulating base 53 is shown as being centrally disposed, and particularly in view of the two attaching members being tissue piercing members. Thus, the components of Edwards are used for a different purpose, in a different device, and for different procedures. The general Office Action allegations are understandably silent as to these very different structural configurations, applications and functionality.

In view of these substantial differences, the alleged combination does not amount to combining elements according to known methods to yield predictable results, simple substitution of elements or use of a known technique to improve a similar product, particularly considering that Edwards describes a device that is designed to not pierce tissue, whereas Hess is structured in an opposite manner to pierce tissue. Further, in view of these different configurations, applications and functionality, it is not obvious to try to use the sensor arrangement shown in Edwards in Hess, particularly since such sensors are an integral part of a catheter and the piercing structure of Hess.

Accordingly, Edwards fails to cure the substantial and deficiencies of Hess such that no proper combination of these references discloses each limitation of each rejected claim, and would not be obvious to combine Hess and Edwards since they describe very different devices that function in substantially different ways for very different, and opposite, purposes. Further, given the particular two tissue piercing / centrally disposed one electrode configuration, Hess teaches away from Applicant's claims.

Therefore, Applicant respectfully submits that independent claims 32-34 are patentable over Hess and Edwards. Dependent claims 14, 17, 19-20, 36, 37, 40-42, 45, 48 and 50-51depend from and incorporate the elements of respective independent claims 32-34 and, therefore, are also patentable over these cited references. References are also deficient relative to various dependent claims.

IV. New Claims

New dependent claims 52 and 53 depend from independent claim 10 and, therefore, are also believed novel and patentable over the cited references for at least the same reasons above.

Claim 52 recites *inter alia* "the first and second stimulation elements are located on

opposite sides of a central portion of the anchor that pierces the tissue at the first location" and claim 53 recites *inter alia* "the first and second stimulation elements are located on opposite sides of a central portion of the flexible carrier that pierces the tissue. As shown in Hess, FIGS. 4 and 7 above, Hess describes an opposite configuration in which the tissue piercing members are not centrally disposed and instead are located on opposite sides of a centrally disposed electrode. In this regard, Hess teaches away from Applicant's new claims.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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